IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TENNESSEE
GREENEVILLE DIVISION

UNITED STATES OF AMERICA and STATE OF TENNESSEE, Plaintiffs, v. WALGREEN CO., Defendant.	Case No. 2:21-CV-00080-JRG-CRW

WALGREEN CO.'S NOTICE OF DEPOSITION TO THE CENTERS FOR MEDICARE AND MEDICAID SERVICES PURSUANT TO FED. R. CIV. P. 30(b)(6)

PLEASE TAKE NOTICE that pursuant to Federal Rule of Civil Procedure 30(b)(6), Defendant Walgreen Co. ("Walgreens") will take the deposition upon oral examination of the federal Centers for Medicare and Medicaid Services ("CMS") on February 18, 2022 at 9:00 a.m. This deposition will take place at the offices of Gibson Dunn, & Crutcher, 1050 Connecticut Avenue N.W., Washington, D.C. 20036. CMS shall designate the person or persons who will testify on behalf of CMS concerning the topics described in Attachment A. Walgreens expects to cover at least Topics 1 through 14 in Attachment A on the noticed date.

The deposition will be recorded by stenographic, audio and video means before an officer authorized to administer oaths, and will continue from day to day, excluding Saturdays, Sundays, and holidays, until completed. The deposition will be taken for purposes of discovery, for use at trial in this matter, and for any other purpose permitted under the Federal Rules of Civil Procedure.

Dated: January 21, 2022

Respectfully submitted,

/s/ Reed Brodsky

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ATTACHMENT A

DEFINITIONS

Unless a contrary meaning appears in context, the following definitions apply:

1. "Action" means the case entitled *United States & State of Tennessee v. Walgreen Co.*, Civil Action No. 21-cv-00080-JRG-CRW, pending in the United States District Court for the Eastern District of Tennessee.

2. "CMS" refers to the federal Centers for Medicare and Medicaid Services, and any person or persons acting on behalf of either or both of them, including but not limited to employees, attorneys, agents, advisors, investigators, and representatives.

3. "Communication(s)" and "communicate(d)" shall mean any oral or written exchange of words, thoughts, or ideas with another person or entity, whether in person, in a group, by telephone, by letter, by fax, by electronic mail, by text message, by instant message, or otherwise. "Communication(s)" and "communicate(d)" shall include, without limitation, correspondence, conversations, dialogues, discussions, consultations, and documents of any type.

4. "Criterion" and "criteria" mean any and all of the following: requirement, prerequisite, standard, qualification, specification, benchmark, practice, instruction, directive, recommendation, suggestion, advice, precedent, or rule in relation to which a given piece of information is evaluated, analyzed, considered, or compared.

5. "Date" means the exact day, month, and year, if ascertainable or, if not, the best approximation of the date (based upon relationship with other events).

6. "Document(s)" shall be construed in the broadest sense possible under the Federal Rules of Civil Procedure, and shall mean all written, printed, typed, transcribed, encoded, punched, recorded, taped, filmed, or other graphic or audio material of every kind and description

whatsoever from which information can be obtained, including without limitation correspondence, tape recordings, videotapes, electronic mail, text messages, and any information stored on computers, computer disks, databases, cellular phones, tablets, and other electronic devices, and removable media of any kind, and shall include all drafts and nonidentical copies of documents.

7. "Document Hold" means an act, process, or mechanism that an organization or individual uses to preserve electronically stored information and/or documents when litigation is reasonably anticipated.

8. Unless otherwise specified, the term "Four DAAs" means one or more of the following direct-acting antiviral medications to treat Hepatitis C: Harvoni®, Sovaldi®, Daklinza®, and Viekira Pak®. The term "Four DAAs" shall be interpreted to include any of these drugs regardless of dosage or method of administration, and regardless of how the document in question refers to them, whether that be by brand name, active ingredient name, national drug code ("NDC"), drug class, or otherwise.

9. "Hepatitis C Medication" means any of the Four DAAs, any Other DAA, and any Non-DAA.

10. "HHS" refers to the U.S. Department of Health and Human Services, all of its components, offices, bureaus, agencies, centers, and other units, and any person or persons acting or who have acted on behalf of any of the foregoing, including but not limited to employees, attorneys, agents, advisors, investigators, and representatives.

11. "Magellan" means Magellan Medicaid Administration, Inc., and any parent, subsidiary, affiliate, predecessor or successor entity of it, any department or business unit of any such entity, and any employee, attorney, agent, advisor, investigator, or representative of any of the foregoing.

12. Unless otherwise specified, the term "Other DAAs" means all other direct-acting antiviral medications indicated for the treatment of Hepatitis C and covered at any time by TennCare (regardless of whether they were ever subject to prior authorization requirements) but not otherwise listed in the definition of "Four DAAs" above. The term "Other DAAs" shall be interpreted to include any of these drugs regardless of dosage or method of administration, and regardless of how the document in question refers to them, whether that be by brand name, active ingredient name, NDC, drug class, or otherwise.

13. "Person" or "persons" means any natural person, corporation, proprietorship, partnership, trust, association, firm, or any other entity, and shall include each and every person or entity, without regard to whether the singular or plural versions of the words person or entity are used.

14. "Plaintiffs" means the United States of America and/or the State of Tennessee, and includes any agency, bureau, department, component, program, office, or authority within the government of either of them, and includes counsel for any such agency (including but not limited to, as applicable, the U.S. Department of Justice, the U.S. Attorney's Office for the Eastern District of Tennessee, and the Tennessee Attorney General's Office), and any bureau, department, component, program, office, or authority within the government of either Plaintiff.

15. "Relating to" and "relate to" mean directly or indirectly mentioning, describing, pertaining to, concerning, embodying, constituting, supporting, corroborating, proving, evidencing, showing, refuting, disputing, rebutting, contradicting, controverting, being connected with, or reflecting upon the subject matter of the specific request.

16. "Release No. 172" means the document entitled Medicaid Drug Rebate Program Notice Release No. 172, *Assuring Medicaid Beneficiaries Access to Hepatitis C (HCV) Drugs*

(Nov. 5, 2015), available at https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/state-releases/state-rel-172.pdf.

17. "Retention Policy" shall mean any policy, procedure, or practice for the preservation or retention of information in the ordinary course of business.

18. "TennCare" refers to the Medicaid program for the State of Tennessee, and any person or persons acting on behalf of it, including but not limited to employees, attorneys, agents, advisors, investigators, and representatives.

19. "Walgreens" means Defendant Walgreen Co., and any parent, subsidiary, affiliate, predecessor or successor entity of it, and any department, business unit, employee or other representative of any of the foregoing.

20. "You," "your," "yours," and "yourselves" mean either yourself, and any person or persons acting or who have acted on your behalf, any other affiliated employees, physicians, attorneys, agents, advisors, investigators, and/or representatives.

21. Except as specifically provided, words imparting the singular shall include the plural and vice versa, and words imparting the present tense shall include the past and future tenses and vice versa, as necessary to give each request its broadest possible meaning.

22. Unless otherwise specified, the relevant time period for the topics below is October 1, 2014 to the present.

DEPOSITION TOPICS

1. The identities, general contents, and general functioning of all databases, systems, servers, and other document or information repositories that are maintained by or for CMS and that contain or may contain information relevant to this Action.

2. CMS's policies, procedures, and practices for determining whether and when to implement Document Holds, and for implementing and enforcing them, including but not limited

to: the persons involved in determining whether, when, and/or how to implement a Document Hold; the criteria and facts considered as part of those decisions; the mechanics of implementing Document Holds and preserving information pursuant to them; and the methods and practices used for verifying compliance with Document Holds.

3. CMS's policies, procedures, and practices for maintaining and retaining information in the ordinary course of business, including but not limited to: Retention Policies; processes and procedures for creating and maintaining data backups; and any other policy, procedure, or practice by which information is maintained or retained.

4. Any training CMS provided to its employees, contractors, or other agents or representatives that is related to information preservation.

5. CMS's knowledge of the investigation that preceded this Action, and the circumstances under which that information was communicated to or learned by CMS, including, but not limited to: the identities of the persons who transmitted and received the information; the entities CMS communicated with about the information; the means used to communicate the information; what information was communicated; and when that information was communicated.

6. The identities of all persons affiliated with CMS who may have information relevant to this Action and/or the investigation that preceded it, as well as the dates of hire and separation, if applicable, for the persons identified.

7. All communications between or among CMS, on the one hand, and any other person, on the other hand, about whether, when, and to what extent a Document Hold should be implemented in connection with this Action and/or the investigation that preceded it.

8. All Document Holds that CMS has implemented in connection with this Action and the investigation that preceded it, including but not limited to, for each Document Hold: the

development of the Document Hold; the subject matters, custodians, document and data repositories, and time periods covered by the Document Hold; the communication of the Document Hold to individual custodians or others with responsibility for information preservation; when and how the Document Hold was implemented; how, if at all, compliance with the Document Hold has been or is being tracked and enforced; and all communications with any person related to the Document Hold.

9. All other Document Holds implemented by CMS in the period from October 1, 2014 to the present that you believe resulted in the preservation of information relevant to this Action, including but not limited to, for each Document Hold: the development of the Document Hold, and the matter(s) in relation to which it was developed; the subject matters, custodians, document and data repositories, and time periods covered by the Document Hold; the communication of the Document Hold to individual custodians or others with responsibility for information preservation; when and how the Document Hold was implemented; and how, if at all, compliance with the Document Hold has been or is being tracked and enforced.

10. All Retention Policies in effect from October 1, 2014 to the present and applicable to persons employed by, contracted with, or affiliated with CMS, including but not limited to, for each Retention Policy: the creation of the Retention Policy; the subject matters, custodians, document and data repositories, and time periods covered by the Retention Policy; the communication of the Retention Policy to individual custodians or others with responsibility for information preservation; how the Retention Policy was implemented; and how, if at all, compliance with the Retention Policy has been or is being tracked and enforced.

11. Any analysis, assessment, study, review, or other consideration, undertaken by or for CMS or the United States, of whether, for any custodian who would potentially possess

information relevant to this Action or to the investigation that preceded it, such information was actually preserved by operation of any Retention Policy or Document Hold.

12. The identity, custodian(s), scope, and volume of any data, documents, or other information that is relevant to this Action or to the investigation that preceded it and that was lost or destroyed before the implementation of any Document Hold or has been destroyed since the implementation of any Document Hold, regardless of whether the Document Hold was tied directly to this Action or not, and the circumstances of such loss or destruction.

13. The preservation of documents or information related to any of the following: Medicaid coverage of DAAs; Release No. 172; any application for a special demonstration project by Tennessee, and any consideration or review by CMS of such a project or such an application therefor; review by CMS of any other documents or materials submitted by Tennessee to CMS related to TennCare's status as a special demonstration project; HHS's authority to grant special demonstration projects, and the process for doing so; and federal financial participation in Medicaid.

14. The custodians and locations of all documents referenced in Topic No. 13 above.

15. For the period from January 1, 2010 to the present, the nature, structure, administration, and oversight of federal financial participation in TennCare, including TennCare's prescription drug benefit.

16. For the period from January 1, 2010 to the present, the development, review, approval, implementation, and revision of all CMS and/or HHS regulations, policies, guidance, and other documentation related to coverage for any Hepatitis C Medication.

17. For the period from January 1, 2010 to the present, the development, drafting, promulgation, and implementation of Release No. 172, including but not limited to the following:

the reasons for developing, drafting, promulgating, and/or implementing Release No. 172; any research or analysis underlying Release No. 172, including but not limited to any research on the effects of fibrosis- and sobriety-based restrictions on access to any of the Four DAAs or any Other DAA; any communications or discussions within CMS or HHS, and/or with persons outside of the federal government, related to the subject matter of Release No. 172; any communications or discussions related to the applicability of Release No. 172 to TennCare; any communications with TennCare relating to Release No. 172; and any review, analysis, consideration, or determination relating to whether and to what extent state Medicaid programs have abided by Release No. 172.

18. For the period from January 1, 2010 to the present, any steps taken by or for CMS, including but not limited to reviews, analyses, or evaluations, related to whether any criteria used, proposed, or considered by any state Medicaid program, including but not limited to TennCare, for coverage of or payment for any Hepatitis C Medication, were consistent with the Social Security Act or the policy goals of the joint federal-state Medicaid program, and/or whether the criteria did or could result in the denial of coverage to Medicaid beneficiaries seeking any medically necessary drug for an FDA-approved indication.

19. For the period from January 1, 2010 to the present, CMS's consideration, analysis, or review of the extent to which, and the reasons for which, the Four DAAs, "based on [their] labeling," do or do not "have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome" over other Hepatitis C Medications, *see* 42 U.S.C. § 1396r-8(d)(4)(C), including but not limited to any reviews, analyses, studies, or communications related to the Four DAAs' clinical superiority over other drugs.

20. For the period from January 1, 2010 to the present, CMS's role, if any, in the development, review, implementation, and/or post-implementation evaluation of TennCare's prior authorization criteria for the Four DAAs, or for any other Hepatitis C Medication.

21. For the period from January 1, 2010 to the present, CMS's role, if any, in training of Magellan and/or TennCare personnel on any topic related to Medicaid coverage for Hepatitis C Medications.

22. For the period from January 1, 2010 to the present, CMS's review of, consultation on, and/or other involvement of any kind related to the activities of TennCare's Pharmacy Advisory Committee, including but not limited to any involvement in the development, review, approval, and implementation of the Preferred Drug List and/or of TennCare's prior authorization criteria for any Hepatitis C Medications.

23. For the period from January 1, 2010 to the present, Medicaid special demonstration projects, including but not limited to the following: the purposes of such projects; the criteria that such projects must satisfy in order to obtain approval from HHS/CMS; the process by which, and criteria according to which, applications for special demonstration projects are evaluated; the process by which, and criteria according to which, special demonstration projects are evaluated once underway; and the extent to which special demonstration projects are permitted to limit access to prescription drugs for Medicaid beneficiaries.

24. For the period from January 1, 2010 to the present, TennCare's status as a special demonstration project, including but not limited to the following: TennCare's application for special demonstration status or for any extension or amendment of it; any notice-and-comment process related to any of the applications; the CMS waiver that Plaintiffs claim governs TennCare; the goals and policy rationales for the waiver, and the reasons for which the waiver was sought;

the budgetary implications of the waiver; any monitoring and/or evaluation of TennCare as a special demonstration project, and any complaints related to TennCare's compliance with the terms of the project; any communications within CMS, between TennCare and CMS, and between CMS and any other person, regarding the extent to which the waiver was intended to effect, and/or did in fact effect, a loosening of federal requirements for access to prescription medications for Medicaid beneficiaries, including but not limited to Hepatitis C Medications; and any review, analysis, consideration, or determination by CMS related to whether and to what extent TennCare's prior authorization criteria for any Hepatitis C Medication were permissible under the waiver.

25. For the period from January 1, 2010 to the present, all actions taken by CMS related to utilization management of the Four DAAs, including but not limited to audits and utilization reviews.

26. All attempts by CMS and/or HHS to identify or quantify the overpayments Plaintiffs allege in the Complaint, and any attempts by CMS and/or HHS to recoup any portions of those overpayments.

27. The Hepatitis C Medicaid Affinity Group, including but not limited to the following: the group's formation, purpose, and activities; criteria for joining and/or participating in the group; the State of Tennessee's participation in the group; Tennessee's status as a "Previous Year Participant" in the group; and any activities, documents, and/or communications by or involving the group and related to Tennessee.

CERTIFICATE OF SERVICE

I hereby certify that on January 21, 2022, Walgreens' Notice Of Deposition To the Centers for Medicare and Medicaid Services Pursuant to Fed. R. Civ. P. 30(b)(6) was served via email and U.S. mail, on the following:

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/s/ Reed Brodsky
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